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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,250	09/08/2003	Dana M. Fowlkes	FOWLKES=4D	1677
7590 10/06/2005			EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 Ninth Street, N.W. Washington, DC 20001			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/656,250	<b>Applicant(s)</b> FOWLKES ET AL.	
	<b>Examiner</b> T. D. Wessendorf	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-146 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-146 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

*Handwritten mark*

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-138 drawn to a method of identifying a ligand (inhibitory ligand) comprising screening a ***combinatorial library***.

Group II, claim 139, drawn to a method of identifying an inhibitory ligand comprising screening a ***structural panel of biased*** combinatorial peptide libraries.

Group III, claim 140, drawn to method of identifying an inhibitory ligand comprising screening a library with the first member ligands all peptides and the first library is an unbiased library or a biased at not more than two amino acid positions.

Group IV, claims 141, drawn to method of identifying an inhibitory ligand comprising screening a combinatorial peptide libraries wherein at least some peptides do not contain internal cys residues.

Group V, claims 142-144 drawn to method of identifying an inhibitory ligand comprising screening a combinatorial

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peptide libraries wherein the ligands do not comprise antibody-like domains.

Group VI, claims 145 drawn to method of identifying a pair of ligands.

Group VII, claim 146 drawn to method of identifying a pair of ligands wherein the ligands are peptides and do not comprise antibody-like molecules.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods using different components and steps that produces different results/ compounds with different effects and/or functions. For example, the method of Group I is drawn to a screening a combinatorial library in an unstructured panel. The method of Group III requires a biased library for which the method of Group I can be a random i.e., unbiased library.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Groups II-VII, specifically the literature journal searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Applicants are to elect a single species from each of the following for whichever group above (I or II or III and etc.) is elected:

A. Combinatorial library as recited in claim 2. If peptide library is elected, a structural formula of the peptide library is required. (See for example claim 7 or claim 14. Each of the variable residues has to be identified. Applicants can refer to the specification for the specific residues that are encompassed by each of the variables Xaa, R1, L, and other variables in the peptide sequence that would make up the combinatorial library and of specific length). The same requirement applies if nucleic acid is the elected member of a library.

B. Structured panel library as recited in claim 6 (or non-structured panel as recited in e.g., claim 1). Applicants are to identify the specific variations (positional residue, type of

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residue and number of residue variants or constants) in a library of the structured panel, for example each library having one and only one constant residues at a first fixed position that is the same for all of the libraries. If the structured panel is elected, applicants are to clearly elect whether a subpanel or not is elected with the panel and to clearly identify the residues as aforementioned.

C. Cys or non-cys containing peptide i.e., linear or cyclic as recited in e.g., claim 11, claim 21, specifically claim 31. Xaa has to be identified.

D. Method by which the first library is obtained as recited in claims 44 (biological means), chemical synthesis as recited in claims 47 (solution phase) or claim 48 (solid).

E. Target as recited in e.g., claims 50-51 and in the other claims that contain a target species.

F. First member ligand as recited in claim 51 i.e., a specific species as recited in claim 53, only one Seq. ID. No. or species from the other claims that contain this limitation.

G. Molecular weight of the second library, a specific molecular weight is required and not relative to the Gly residue as recited in e.g., claim 107.

H. Second library as recited in e.g., claim 123 or in other claims that contain this limitation. However, applicants are

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reminded that this library has to be specific compounds not a genus e.g., heteronitrogen.

Each of the species covered in each of the genus e.g., subgroup A differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species( i.e., one from subgroup A, one from B and so on) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 139-142 and 145-146 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant

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must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

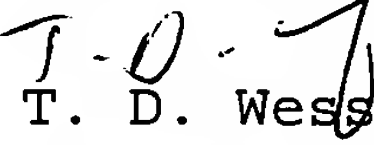


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

October 1, 2005